

**UNITED STATES DISTRICT COURT**  
**FOR THE EASTERN DISTRICT OF CALIFORNIA**

ASSOCIATION FOR ACCESSIBLE  
MEDICINES,

Plaintiff,

- against -

XAVIER BECERRA, in his official capacity  
as Attorney General of the State of California,

Defendant.

Case No. 2:20-cv-01708-TLN-DB

**MEMORANDUM OF LAW IN SUPPORT OF**  
**PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

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## INTRODUCTION

When the Association for Accessible Medicines (“AAM”) first brought suit challenging the constitutionality of California Assembly Bill No. 824 (“AB 824”), this Court recognized that it “would likely violate the Dormant Commerce Clause” “if the Attorney General were to enforce the terms of AB 824 against two out of state parties that entered into a settlement agreement outside of California, having nothing to do with California.” CA9.ER8. There is no longer any doubt that the Attorney General (“AG”) intends to do just that. At oral argument in the Ninth Circuit, counsel for the AG confirmed that it “intends to enforce this law with respect to agreements made outside the borders of California.” July 16, 2020 Notarized Oral Argument Tr. (Ex. A) at 22:10–23:24. And, as the accompanying declarations confirm, multiple AAM members have already suffered concrete economic harm as a result of AB 824. It is now crystal clear that AB 824 has altered the course of settlement negotiations in pending and recently concluded patent suits litigated wholly outside of California; has caused AAM members to accept less favorable settlement terms; and has forced them to continue litigating infringement cases rather than settle, costing them considerable amounts of money both in terms of legal fees and lost opportunities.

Since its enactment, AB 824 has stymied settlement efforts in a number of pending patent cases. For example, one AAM member manufacturer is “currently a defendant in a patent suit” “in Delaware” that “would have settled if AB 824 was not in effect.” Ex. D ¶¶ 3-5. The parties to the patent suit there “negotiate[d] a settlement under which [the AAM member] would have received some financial consideration ... plus a license to bring its generic onto the market prior to [patent] expiration,” “but not immediately.” *Id.* ¶ 4. “Because of AB 824, ... however, the parties have so far been unable to conclude the settlement,” leaving the member “continuing to pay its lawyers to” defend the suit and depriving the member of “the value it would have received under the ... settlement.” *Id.* ¶¶ 4-5.

That member hardly stands alone. A second AAM member recently “decided to pull out of” “a tentative settlement agreement, under which the defendant would have received consideration and would have been allowed to bring its generic product onto the market” “not immediately,” but “prior to the expiration of the patent,” “because of [its] concern about the enforcement of AB 824 as it would apply to [the] settlement in light of AB 824’s provision deeming exclusive licenses to be things of value.” Ex. E

¶¶ 4-5; *see* § 134002(a)(1). This member is thus also “continu[ing to] litigat[e]” a case it would have settled but for AB 824, “at considerable cost in terms of legal fees.” Ex. E ¶ 5.

Another AAM member in a similar position likewise “has not settled” a patent suit pending “in Delaware” “because of concern over the scope and impact of AB 824.” Ex. C ¶¶ 5-6. Specifically, “the California [AG]’s stated intent to enforce AB 824 against patent settlements negotiated, signed, and entered wholly [out of state]” led the parties to break off settlement talks, causing this member to “continue[]” spending money “to litigate” rather than risk “being haled into California court” and potentially face “the massive monetary penalties that AB 824 imposes.” *Id.* ¶¶ 6-7.

A fourth AAM member has expended more than a quarter-million dollars in legal fees that it “would not have incurred ... but for AB 824.” Ex. B ¶ 12. This member too is a defendant in a pending patent suit. A tentative agreement was struck “under which [the plaintiff] would grant [this member] ... a license to enter the market approximately [5] years and [8] months prior to patent expiry,” but not immediately, plus “a Most Favored Nations (MFN) clause, which would have permitted [it] to launch its generic drug even earlier under certain circumstances.” *Id.* ¶ 7. “Because of AB 824, however, [the plaintiff] withdrew the offer of an MFN clause,” *id.* ¶ 9, which it had included in settlements “prior to AB 824,” *id.* ¶ 10. That AB 824–driven withdrawal has caused the AAM member “to continue litigating the case, at enormous cost” in terms of fees it would not have expended but for AB 824. *Id.* ¶ 11; *see id.* ¶ 12.

Any questions of standing or ripeness are now answered. As the new declarations filed alongside this Memorandum illustrate, multiple AAM members have already suffered concrete economic harm as a direct result of AB 824. And as the AG’s concession at oral argument in the Ninth Circuit confirms, the AG fully intends to enforce AB 824 against pharmaceutical manufacturers based on patent settlements completed entirely out of state. AAM is thus likely to succeed on the merits of its dormant Commerce Clause claim. *See* CA9.ER8 (concluding that it “would likely violate the Dormant Commerce Clause” “if the [AG] were to enforce the terms of AB 824 against two out of state parties that entered into a settlement agreement outside of California, having nothing to do with California”). AAM is also likely to succeed on its claims under the Supremacy Clause, Excessive Fines Clause, and Due Process Clause.

The remaining factors likewise favor injunctive relief. AB 824 exponentially raises the risks and potential costs of settling patent suits. It has already forced AAM’s members to expend unnecessary

resources litigating patent cases, and has already caused them to lose opportunities to bring their lower-priced medicines onto the market prior to patent expiry. These injuries are irreparable by definition, given the AG’s Eleventh Amendment protection. And subjecting AAM’s members to an unconstitutional law causes irreparable harm on its own. In short, AAM’s members will “suffer irreparable harm in the absence of preliminary relief.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Finally, the balance of equities and public interest support injunctive relief as well. Enforcement of an unconstitutional law is always contrary to the public interest, and a state and its officers suffer no cognizable harm by being enjoined from enforcing an unconstitutional law. And even putting the merits to the side, AB 824 has already caused generic manufacturers to walk away from (or be denied the opportunity to enter into) settlements that would have permitted their lower-priced, but equally safe and effective, medicines to enter the market prior to patent expiry, and to withdraw new generic drug applications altogether. Enjoining AB 824 will help ensure that patients have timely access to the low-priced, life-saving medicines they need. For these reasons, and as further set forth below, the Court should grant AAM’s motion.

## STATEMENT OF FACTS

### A. Patent Settlements Save Americans Billions of Dollars in Healthcare Costs.

Access to generic and biosimilar medicines is critical to ensuring that Americans have affordable healthcare. In 2018, generic medicines accounted for 90% of the prescriptions dispensed in the United States (up from 75% in 2009), but just 22% of total drug spending. Ass’n for Accessible Meds., *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 4 (2019), <https://bit.ly/2ojfghJ>. The savings are staggering: Generic alternatives to brand-name drugs saved Americans nearly \$2 trillion over the last decade, and almost \$300 billion in 2018 alone. *Id.*

Much of these savings would not have been possible without patent-litigation settlements. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”), Pub. L. No. 98-417, 98 Stat. 1585, generic versions of previously-approved brand-name drugs may obtain FDA approval through streamlined and less expensive abbreviated new drug applications (“ANDAs”), which “show[] that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug.” *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). But “the

1 FDA cannot authorize a generic that would infringe a patent,” so “a company filing an ANDA must assure  
2 the FDA that its proposed generic drug will not infringe the brand’s patents.” *Id.* at 406.

3 A common option for providing that assurance “is to file a so-called paragraph IV certification,  
4 which states that a listed patent ‘is invalid or will not be infringed by the manufacture, use, or sale of the  
5 [generic] drug.’” *Id.* at 407 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). “Filing a paragraph IV  
6 certification,” however, “means provoking litigation,” as the Patent Act “treats such a filing as itself an  
7 act of infringement.” *Id.* Patent litigation, therefore, is engineered by federal law as a stepping stone on  
8 the pathway that generic medicines must travel to lawfully enter the market. (The market-entry pathway  
9 for biosimilars is analogous. *See* Biologics Price Competition and Innovation Act of 2009 (“BPCIA”),  
10 Pub. L. No. 111-148, § 262(i)(2)(A), (I), 124 Stat. 119.)

11 Unfortunately, “the cost of litigation in this specific context,” *i.e.*, “a generic challenging a brand  
12 name pharmaceutical patent,” is staggering. *FTC v. Actavis, Inc.*, 570 U.S. 136, 170 (2013) (Roberts, C.J.,  
13 dissenting). The cost “was about \$10 million per suit” as of 2010, *id.*, and it has sharply increased since  
14 then, *see, e.g.*, Malathi Nayak, *Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*,  
15 BLOOMBERG LAW (Sept. 10, 2019) (cost rose 67% between 2015 and 2019), <https://bit.ly/2ki106U>. Such  
16 suits are also notoriously difficult for generic manufacturers to win. When Paragraph IV cases are litigated  
17 to judgment (as opposed to settling beforehand), generic manufacturers prevail far less than half the time.  
18 *See* Lex Machina, *Pharmaceutical Patent Litigation Increases Nearly 30 Percent in 2017: Lex Machina*  
19 *Releases Fourth Hatch-Waxman/ANDA Litigation Report* (May 3, 2018), <https://bit.ly/2JnHSxo>. And, if  
20 the generic manufacturer does not prevail, then its product is barred from the market for the entire  
21 remaining life of the patent covering the brand-name drug. 35 U.S.C. § 271(e)(4)(A).

22 Even when a brand-name drug is protected by only one patent, the expected costs of litigating to  
23 judgment will thus often outweigh the expected value for the generic manufacturer. Yet it is increasingly  
24 rare for a brand-name drug to be protected by just one patent. Brand-name drug companies often file what  
25 are known as “follow-on” patent applications, which, if granted, extend their exclusivity for many more  
26 years—and thus multiply the cost of patent litigation many times over. Robin Feldman, *May Your Drug*  
27 *Price Be Evergreen*, 5 J. L. & BIOSCI. 590 (2018), <https://bit.ly/3iOh34N>. Armed with a portfolio of  
28

1 follow-on patents, brand-name drug companies can dramatically increase the cost of bringing a new  
 2 generic medicine onto the market through the expedited pathway federal law provides.

3 Patent settlements, which can resolve claims on all patents protecting a brand-name drug, are thus  
 4 often indispensable in enabling timely generic entry. Indeed, if generic manufacturers had to litigate every  
 5 patent blocking their entry to final judgment, then few generic medicines would timely enter the market—  
 6 not only because there would be fewer successful outcomes, but also because the expected cost, delay,  
 7 and risk of failure would deter generics from bringing patent challenges in the first place, knowing that  
 8 such challenges usually “provok[e] litigation.” *Caraco*, 566 U.S. at 407.

9 **B. Contrary to *Actavis*, AB 824 Presumes Unlawful Run-of-the-Mill Settlements.**

10 AB 824 substantially departs from the regime Congress envisioned and *Actavis* respected. Under  
 11 AB 824, “an agreement resolving or settling ... a patent infringement claim, in connection with the sale  
 12 of a pharmaceutical product, shall be presumed to have anticompetitive effects and shall be a violation of  
 13 this section” whenever the generic (A) “receives anything of value from [the brand] company” and  
 14 (B) “agrees to limit or forego ... sales of [its] product for any period of time.” § 134002(a)(1). The statute  
 15 defines the term “anything of value” broadly. Although it excludes a few narrow forms of compensation,  
 16 *see* § 134002(a)(2), AB 824 specifically “includ[es]” *any form of “exclusive license”* in the definition of  
 17 “anything of value,” § 134002(a)(1)(A) (emphasis added).

18 That is a stark departure from federal law and longstanding practice. Exclusive licenses—which  
 19 AB 824 deems presumptively unlawful (except in the exceedingly rare case in which the settlement allows  
 20 a generic to enter the market *immediately upon settlement*, *see* § 134002(a))—are the bread-and-butter of  
 21 patent settlement agreements. Not only does the Patent Act protect the right to grant exclusive licenses,  
 22 *see* 35 U.S.C. § 261, but the Hatch-Waxman Act makes short-term exclusivity the main mechanism to  
 23 induce generic manufacturers to challenge the patents protecting high-priced brand-name drugs. Indeed,  
 24 the entire federal regulatory apparatus governing generic prescription drugs is premised on the notion that  
 25 generic manufacturers need short-term exclusivity to be willing to spend the time and money necessary to  
 26 challenge the patents blocking high-priced brand-name drugs. Furthermore, because it measures delay  
 27 from the date a settlement is entered, not what would have happened if the parties had litigated the patent  
 28 case to judgment, AB 824 renders presumptively unlawful a host of previously commonplace settlement

1 terms. Even accelerator clauses—under which a manufacturer may bring its generic medicine onto the  
 2 market even earlier if certain specified events occur—are presumed to be unlawful transfers of value  
 3 (again except where the generic may enter the market immediately and without exclusivity). *But see, e.g.,*  
 4 R. & R. 20-22, *In re Sensipar Antitrust Litig.*, No. 19-md-2895 (D. Del. July 23, 2020), Dkt. 160 (MFN  
 5 acceleration provision is not a “reverse payment” and thus is exempt from scrutiny under *Actavis*).

6 Rebutting AB 824’s presumption of anti-competitiveness is daunting. A settling party must prove  
 7 that “[t]he value received by the [generic]” under the agreement “is a fair and reasonable compensation  
 8 solely for other goods or services that [the generic] has promised to provide,” or that “[t]he agreement has  
 9 directly generated procompetitive benefits” that “outweigh [its] anticompetitive effects.” § 134002(a)(3).  
 10 The fact that a settlement “*will* have procompetitive effects” once the generic enters the market “is not  
 11 sufficient to rebut the antitrust presumption,” even if the settlement’s net effect is procompetitive in the  
 12 long run. CA9.ER21. In determining whether a defendant has rebutted the presumption, moreover,  
 13 factfinders may not presume, *inter alia*, that generic entry “could not have occurred until the expiration of  
 14 the relevant patent[s],” or that “entry of the [generic] product before the expiration of any patent  
 15 exclusivity means that the agreement is procompetitive.” § 134002(b)(1). And, whereas federal patent  
 16 law specifically provides that “[a] patent shall be presumed valid,” 35 U.S.C. § 282(a), AB 824 explicitly  
 17 prohibits factfinders from presuming “[t]hat any patent is enforceable,” § 134002(b)(2).

18 AB 824 also includes draconian penalties, which are in addition to “any relief or damages” that  
 19 may be available under California’s preexisting competition laws. § 134002(e)(2)-(3). A party that  
 20 violates AB 824 and “received any value due to that violation” “shall forfeit and pay to the State of  
 21 California a civil penalty” of “three times the value received by the party that is reasonably attributable to  
 22 the violation ..., or [\$20 million],” “whichever is greater.” § 134002(e)(1)(A)(i); *see*  
 23 § 134002(e)(1)(A)(iii). And each “person” who even merely “assists in [a] violation” must pay at least  
 24 \$20 million, even if he or she “has not received anything of value.” § 134002(e)(1)(A)(ii).

## 25 JURISDICTION

26 AAM challenges the validity of AB 824 under 42 U.S.C. § 1983 and the United States  
 27 Constitution. This Court has jurisdiction under 28 U.S.C. § 1331.  
 28

## ARGUMENT

“Plaintiffs seeking a preliminary injunction must establish that: (1) they are likely to succeed on the merits; (2) they are likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in their favor; and (4) an injunction is in the public interest.” *Short v. Brown*, 893 F.3d 671, 675 (9th Cir. 2018). Each factor favors injunctive relief here.

### I. AAM Is Likely To Succeed On The Merits.

#### A. AB 824 Violates the Dormant Commerce Clause.

1. There is no longer any question that the AG intends to enforce AB 824 against settlements completed out of state, or that AAM’s dormant Commerce Clause claim is ripe for adjudication. At oral argument in the Ninth Circuit in the initial round of litigation challenging AB 824, Judge Hurwitz asked counsel for the AG point blank, “[D]oes California intend to enforce this statute in the case of agreements made out of state?” Ex. A at 22:10-12. After counsel failed to answer the question directly, Judge Hurwitz asked again, “whether or not [the AG] intends to enforce this law with respect to agreements made outside the borders of California.” *Id.* at 22:18-23. Counsel for the AG finally responded: “Your honor, yes.” *Id.* at 23:12. That is more than enough to satisfy Article III for purposes of AAM’s dormant Commerce Clause claim—particularly in light of the new declarations accompanying this Memorandum, which plainly state that AB 824 has already altered the course of settlement negotiations in out-of-state cases and has already caused AAM members to decline or lose favorable settlement offers *and thus to spend huge sums litigating that they otherwise would not have spent*. See, e.g., Ex. D ¶¶ 4-5; Ex. E ¶¶ 3-5.<sup>1</sup>

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<sup>1</sup> The AG’s concession regarding its intent to enforce AB 824 against parties even for entering into patent settlement agreements completed wholly out of state should be unsurprising, because it is consistent with the plain text of the statute. On its face, AB 824 applies to settlement agreements completed outside of California. None of AB 824’s operative provisions contains any limitation on the statute’s application to patent settlements completed wholly out of state. Neither do its \$20-million penalty provisions. See § 134002(e)(1)(A)(i)-(ii). The closest thing to a state nexus in the statute is § 134002(e)(1)(A)(iii), which is the provision setting the upper limit for penalties above the \$20-million minimum. But AB 824 in no way limits its *substantive* restrictions on patent settlements to those settlements that have a California nexus (as opposed to those settlements relating to pharmaceutical products that are sold in California). See § 134002(a)-(b). And AB 824 unambiguously imposes a minimum \$20-million penalty without regard to whether the offending settlement agreement has any California nexus or impact. § 134002(e)(1)(A)(i)-(ii). In short, AB 824 applies to settlements completed wholly outside California.

1 That economic injury stemming from forbearance from commercial activities that AAM's  
 2 members "would otherwise" engage in (namely, settlements that (1) contain a thing of value as that term  
 3 is defined in AB 824, but (2) do not allow for immediate generic entry) is exactly the sort of injury that  
 4 the Ninth Circuit has recognized as sufficient for Article III standing in this context. *See, e.g., Nat'l*  
 5 *Audubon Soc'y, Inc. v. Davis*, 307 F.3d 835, 855-56 (9th Cir. 2002) (trappers "satisf[ied] all three  
 6 requirements of Article III standing" in challenge to new law that penalized certain trapping activity based  
 7 on their having suffered economic injury as a result of abstaining from conduct that the challenged law  
 8 penalized and that "they would otherwise" have engaged in but for the new law); *Bland v. Fessler*, 88 F.3d  
 9 729, 737 (9th Cir. 1996) (foregone revenue caused by compliance with unconstitutional statute "under the  
 10 cloud of the civil statute's penalties" created a live controversy sufficient for Article III).<sup>2</sup>

11 This Court previously suggested that a "prudential inquiry" led it to find that AAM's dormant  
 12 Commerce Clause claim was unripe, because "additional facts [we]re necessary to address the Commerce  
 13 Clause question." CA9.ER10-11. But regardless of whether prudence counseled in favor of that  
 14 conclusion in the prior round of litigation—and regardless of whether such a prudential inquiry is even  
 15 appropriate as a general matter, *but see Clark v. City of Seattle*, 899 F.3d 802, 809 n.4 (9th Cir. 2018) ("The  
 16 Supreme Court recently cast doubt on the prudential component of ripeness in *Susan B. Anthony*  
 17 *List[.]*")—prudence now is firmly on AAM's side. The issues presented by AAM's challenge are purely  
 18 legal and turn on the extraterritorial reach established by the text of AB 824, *which the AG has conceded*.  
 19 And consistent with the AG's stated intent, AAM's members *have already* suffered economic injury.

20 3. Nor is there any question that enforcing AB 824 against out-of-state settlements would  
 21 constitute direct regulation in violation of the dormant Commerce Clause. The dormant Commerce Clause  
 22 prohibits states from "regulating commerce occurring wholly outside [their] borders." *Healy v. Beer Inst.*,  
 23 491 U.S. 324, 332 (1989). This prohibition applies whether or not the "extraterritorial reach was intended"  
 24 and whether or not the out-of-state transaction "has effects within the State." *Id.* at 335-36 (citations  
 25 omitted). Indeed, the prohibition against direct regulation of transactions completed out of state applies

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26  
 27 <sup>2</sup> "[T]he three-factor test applied in *Thomas v. Anchorage Equal Rights Commission*, 220 F.3d 1134  
 28 (9th Cir. 2000) (en banc)," does not control when—as here—plaintiffs allege "tangible economic injury"  
 due to the challenged law arising from forbearance of economic activity. *Davis*, 307 F.3d at 855.

not just when a state law *explicitly* regulates extraterritorially, but also even when only “the practical effect of [a] regulation is to control conduct beyond the boundaries of the State.” *Id.* at 336.

*Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935), is instructive. At issue there was a wholesale transaction between a Vermont “creamery” (manufacturer) and a New York “milk dealer” (wholesaler). *Id.* at 518. All of the milk sold in that Vermont transaction was intended for resale in New York. Indeed, the New York statute challenged in the case “applied only to milk that would eventually be sold to New York consumers.” *Carolina Trucks & Equip., Inc. v. Volvo Trucks of N. Am., Inc.*, 492 F.3d 484, 491 (4th Cir. 2007). Yet that limitation did not save the statute from invalidation. The statute mandated that “milk bought outside” New York could not be sold “within the state” unless the price paid in the out-of-state transaction conformed to the price requirements New York imposed “upon a like transaction within the state.” *Baldwin*, 294 U.S. at 519. And the practical effect of that prohibition was to impose New York-law requirements on out-of-state transactions. The Supreme Court therefore struck the statute down, even though the out-of-state transactions it regulated had clear, undisputed effects within the state. *Id.* at 521.

The law of this Circuit is in accord, as *Sam Francis Foundation v. Christies, Inc.*, 784 F.3d 1320 (9th Cir. 2015) (en banc), makes clear. *Sam Francis* involved a challenge to California’s Resale Royalty Act, which “requires the seller of fine art to pay the artist a five percent royalty if ‘the seller resides in California or the sale takes place in California.’” *Id.* at 1322 (quoting Cal. Civ. Code § 986(a)). The plaintiffs argued that the statute was unconstitutional with respect to “sales outside the state of California.” *Id.* The Ninth Circuit fully agreed—even though the statute regulated out-of-state sales only when they involved a California resident, and even though “in some circumstances, the royalty amount eventually may wind up ... in a special fund of the State’s coffers. *Id.* at 1324. Those “connection[s] with the state” did not save the statute because—as *Baldwin* makes clear—the “constitutional rule” applied in *Healy* operates without exception: “[W]hether or not the commerce has effects within the State,” California may not “regulate[] a commercial transaction that ‘takes place wholly outside [its] borders.’” *Id.* at 1323-25 (quoting *Healy*, 491 U.S. at 336); accord, e.g., *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 612-16 (9th Cir. 2018); *Nat’l Collegiate Athletic Ass’n v. Miller*, 10 F.3d 633, 639 (9th Cir. 1993).

AB 824 cannot be reconciled with that well-settled case law. Although the AG has previously argued that AB 824 regulates prescription-drug sales in California (or, alternatively, “practice[s]” that

“delay ... generic competition in California[],” CA9.AG.Br.35-36), the statute in fact regulates one thing and one thing only: pharmaceutical patent settlements. The only thing that can “be a violation of [AB 824]” is “an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product,” § 134002(a)(1)—*i.e.*, a settlement between a brand-name drug company and the manufacturer of a competing generic/biosimilar pharmaceutical. *See also* Ex. A at 28:14-20 (“[T]he statute ... regulate[s] the entering into the agreement, ... not the subsequent marketing in California.”). Thus, even if one (atextually) construed the statute to apply to out-of-state settlements only once a drug covered by the settlement was sold in the state, the Commerce Clause *still* would prohibit the AG from enforcing AB 824 against settlements completed out of state. *See Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986) (that a state law “is addressed only to sales ... in [the state] is irrelevant if [its] ‘practical effect’” is to regulate conduct “in other States”).

The conflict with the dormant Commerce Clause here is stark. If two parties settle a patent suit in Delaware on terms that AB 824 deems unlawful, the settling parties (and every person who merely assists) would be liable for severe penalties under California law. *See* § 134002(a), (e). And the definition of “directly regulating” commerce for dormant Commerce Clause purposes is “impos[ing] civil or criminal penalties on non-compliant transactions completed wholly out of state.” *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1102-03 (9th Cir. 2013). Indeed, even if parties settle out of state on terms that AB 824 deems only *presumptively* unlawful, those parties will *still* be directly regulated by California even if they are ultimately able to rebut the presumption and defeat the AG’s enforcement action. In sum, enforcing AB 824 against a settlement completed out of state—which the AG is now on record as planning to do—is unconstitutional *even if* the settlement “has effects within the State.” *Healy*, 491 U.S. at 336.

## **B. AB 824 Is Preempted.**

1. AB 824 conflicts directly with two critical provisions of the Patent Act by (1) treating as presumptively unlawful the mere exercise of the federally conferred right to grant an exclusive license, *compare* AB 824 § 134002(a)(1)(A), *with* 35 U.S.C. § 261, and (2) erasing the ordinary federal presumption of patent validity, *compare* AB 824 § 134002(b)(2), *with* 35 U.S.C. § 282(a).

First, whereas the Patent Act gives patent holders the right to grant exclusive licenses, *see* 35 U.S.C. § 261, AB 824 expressly defines a reverse payment (“anything of value”) to “includ[e]” “an

exclusive license,” § 134002(a)(1)(A). In other words, under AB 824, a pharmaceutical patent settlement that contains an exclusive license *and nothing more* is presumptively suspect unless it permits the generic manufacturer to bring its generic medicine onto the market immediately (*i.e.*, the moment the settlement is finalized). That conflict is particularly stark. After all, the Supreme Court has long recognized the validity of exclusive licenses, *see, e.g., Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938); *Actavis* clearly admonished that such rights should be respected, *see* 570 U.S. at 158; and *even the FTC* acknowledges that settlements with exclusive licenses and early-but-not-immediate entry tend to be procompetitive, *see, e.g., Br. of FTC as Amicus, Am. Sales Co. v. Warner-Chilcott Co., LLC*, 2015 WL 3957874, at \*29 (1st Cir. June 16, 2015). *Cf. Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 578, 605 n.21 (N.D. Cal. 2020) (recognizing that “not ... every exclusive license may be subject to antitrust scrutiny”).

Second, whereas the Patent Act requires that “patent[s] shall be presumed valid” and enforceable, 35 U.S.C. § 282(a), AB 824 prohibits factfinders from presuming that “any patent is enforceable,” § 134002(b)(2). AB 824 thus directly diminishes the value of a federally conferred patent—and, accordingly, the fact that “AB 824 is not offering patent-like protection,” CA9.ER13, does not save it from invalidation under the Supremacy Clause. For while “the Patent Act does not preempt every state commercial law that touches on intellectual property,” *In re Cybernetic Servs., Inc.*, 252 F.3d 1039, 1046 (9th Cir. 2001), *all* state laws—including state laws regulating competition—must yield to the extent that [they] clash[] with the balance struck by Congress in our patent laws.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989); *see also Morseburg v. Balyon*, 621 F.2d 972, 977 (9th Cir. 1980) (state laws regulating “competition” “have long been “held to be preempted by the federal patent law” when they “upset the federally struck balance”). Hence, the Supreme Court held in *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001), that federal patent law “impliedly pre-empted” state-law “fraud-on-the-FDA claims” *even though the state law authorizing those tort claims did not provide patent-like protection*, because “allowing” plaintiffs to bring such tort claims against patent holders would “skew[]” the “delicate balance of statutory objectives” the federal patent laws establish. *Id.* at 348. The same reasoning applies here: In foreclosing the federal presumption of validity and enforceability, AB 824 undermines federal patent protections and skews the delicate balance at the heart of federal patent law.

2. In addition to conflicting with Patent Act directly (and thereby diminishing the value of a federally conferred intellectual property right), AB 824 also conflicts with the federal balance at the heart of the federal laws regulating the market-entry mechanism for generic pharmaceuticals. “The Supreme Court’s preemption case law indicates that ... a finding of conflict preemption” is particularly likely when the regulatory environment demands “a balance between competing statutory objectives.” *Farina v. Nokia Inc.*, 625 F.3d 97, 123 (3d Cir. 2010); *see, e.g., Buckman*, 531 U.S. at 348 (preempting “fraud-on-the-FDA claims under state tort law” because “allowing” such claims could “skew[]” the “delicate balance of statutory objectives” in play). Such is the case here. As noted, the Patent Act “balance[s] ... the interest in motivating innovation ... by rewarding invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition.” *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). The Hatch-Waxman Act likewise “balance[s]” competing federal objectives—namely, (1) “the goal of ‘mak[ing] available more low cost generic drugs,’ with [(2)] the value of patent monopolies in incentivizing beneficial pharmaceutical advancement.” *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (citation omitted). AB 824 throws a massive wrench into the federal-law mechanisms that promote and protect that latter balance of interests.

To be clear: The laws that preempt here are the federal patent laws and laws regulating generic and biosimilars, which themselves reflect and respect a balance between competing federal objectives. And, as evidenced by cases like *Connell Construction Co. v. Plumbers & Steamfitters Local Union No. 100*, 421 U.S. 616, 635-36 (1975), which held that a claim arising under state antitrust law was preempted by federal labor law even though the conduct that gave rise to the claim could proceed under federal antitrust law, even state laws regulating “competition” have long been “held to be preempted by the federal patent law[s]” when—as here—they “upset the federally struck balance.” *Morseburg*, 621 F.2d at 977.

Patent settlements and short-term restrictions on inter-generic competition are not just permissible under the Hatch-Waxman Act, but central to its aims. In enacting the Hatch-Waxman Act, Congress recognized and reflected two basic facts: *first*, patent settlements are often necessary to get generic medicines onto the market prior in a timely manner, given that brand-name drugs are often protected by multiple patents that cannot be invalidated in a single patent-infringement case; and, *second*, generic manufacturers will rarely be willing to “stick out their necks” and induce patent-infringement lawsuits

1 unless there is a “reward” for doing so, given the sky-high costs of patent litigation in this context, the  
 2 presence of patent portfolios, and the fact that generic manufacturers prevail less than half of the time  
 3 when these type of patent suits are litigated to judgment. *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d  
 4 1303, 1318 (D.C. Cir. 2010). In light of those two basic facts, Congress made the first filer of a  
 5 substantially complete paragraph IV ANDA eligible for a 180-day exclusivity period, *see* 21 U.S.C.  
 6 § 355(j)(2)(A)(vii)(IV), (j)(5)(B)(iv), and thus provided generic manufacturers an economic incentive to  
 7 induce patent litigation and therefore patent settlements. The balance Hatch-Waxman strikes, in other  
 8 words, is to briefly restrict inter-generic competition to “induce challenges to patents claimed to support  
 9 brand drugs” and thereby obtain a “pro-consumer” result. *Teva*, 595 F.3d at 1318. “Indeed, it is [this]  
 10 special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing  
 11 more drugs more quickly and cheaply to the public.” *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 626 (2011).

12 AB 824 turns that balance on its head. Whereas Hatch-Waxman expressly blesses the concept of  
 13 giving a generic the exclusive right to enter the market (which restricts competition) for a period of time,  
 14 AB 824 presumes that arrangements between brands and generics that include “an exclusive license” are  
 15 unlawful as a matter of state law. *See* § 134002(a). AB 824 also inverts the burden of proof in challenges  
 16 to patent settlements, making the standard of review more favorable to the state-party challenging a  
 17 settlement as allegedly anticompetitive. That inversion makes it far more likely that patent settlements  
 18 will be challenged, and far more difficult for settling parties to defend themselves—which, in turn, will  
 19 make manufacturers far less eager to settle patent suits, a phenomenon we have already seen. That is  
 20 especially true given that AB 824 imposes penalties far above what were previously available under state  
 21 and federal law, *including penalties against individual persons who merely assist in a settlement*. That  
 22 makes settling patent cases far riskier and far more costly for companies—not to mention their executives,  
 23 employees, and agents. Add it all up, and AB 824 increases the expected cost of settling a patent suit,  
 24 which in turn will decrease the incidence of settlement—which is the whole point of the statute—and  
 25 thereby inhibit the flow of generic medicines onto the market. *Cf. Amgen Inc. v. Sandoz Inc.*, 877 F.3d  
 26 1315, 1329 (Fed. Cir. 2017) (concluding that subjecting biosimilar manufacturers to “‘the shadow of 50  
 27 States’ tort regimes,’ and unfair competition standards, could ‘dramatically increase the burdens’ on [them]  
 28 beyond those contemplated by Congress” (quoting *Buckman*, 531 U.S. at 350)).

1 To be sure, AB 824 does not outlaw patent settlements. But a law need not forbid certain  
 2 transactions to make those transactions costlier. And a law that makes it costlier to enter into transactions  
 3 that help speed generics onto the market will inevitably diminish the incidence of such transactions, and  
 4 thus the incidence of generics entering the market prior to patent expiry. *See generally* Richard A. Posner,  
 5 *Economic Analysis of Law* 5 (4th ed. 1992). Because that is exactly what it will do—and, indeed, *already*  
 6 *has done*, as the accompanying declarations make clear, *see, e.g.*, Ex. D ¶¶ 4-5; Ex. E ¶¶ 3-5; *see also* Ex.  
 7 F ¶ 9—AB 824 is fundamentally at odds with the Hatch-Waxman Act, and preempted on that basis.

8 3. AB 824 is also preempted to the extent it purports to apply to patent settlements involving  
 9 biologics and biosimilars under the BPCIA. The subject matter of the BPCIA (*i.e.*, biosimilar approval  
 10 and related patent litigation) involves “a scheme of federal regulation so pervasive” that there remains no  
 11 role for state law to play. *Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 196 F.3d 1366, 1372 (Fed.  
 12 Cir. 1999). Indeed, not only do the BPCIA’s “carefully crafted and detailed” patent-litigation provisions  
 13 create a comprehensive procedural roadmap and specific consequences for departing from it, but they  
 14 “intentionally” limit injunctive relief to one circumstance and provide no damages remedy *at all*. *Sandoz*  
 15 *Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1674-75 (2017). Hence, the Federal Circuit recently held that state  
 16 regulation of “biosimilar patent litigation” is categorically off-limits, as “the federal government has fully  
 17 occupied this field”—and, specifically, held that allowing state unfair competition claims to be brought  
 18 against parties for settling biosimilar patent litigation would “intrude upon a field, biosimilar patent  
 19 litigation, that Congress reserved for the federal government.” *Amgen*, 877 F.3d at 1328-30. So too here.

20 4. Finally, AB 824 is radically inconsistent with the federal balance struck in the Patent Act  
 21 and respected in *Actavis*. Under *Actavis*, antitrust review of patent settlements is permitted only if a  
 22 settlement has a “large and unjustified” payment from the patent holder to the patent challenger—and  
 23 even then, only pursuant to the rule of reason. 570 U.S. at 158-59. Under AB 824, by contrast, review is  
 24 permissible by default, except in the rare class of cases in which the settlement grants the generic a  
 25 nonexclusive license *and* permits the generic to enter the market immediately. What is more, whereas  
 26 *Actavis* requires the party challenging a patent settlement to prove that the settlement *in fact* has already  
 27 had anticompetitive effects, AB 824 presumes that critical element. *See* § 134002(a)(1).  
 28

1 This is not a context in which states are free to impose antitrust restrictions that go beyond the  
 2 federal regulatory floor. To the context, *even the California Supreme Court* has acknowledged that “[t]he  
 3 United States Supreme Court is the final arbiter of...the extent to which interpretations of antitrust law—  
 4 whether state or federal—must accommodate patent law’s requirements,” and, as such, that California  
 5 “must abide by [Actavis’s] judgment” on how to balance the competing federal interests patent settlements  
 6 implicate. *In re Cipro Cases I & II*, 348 P.3d 845, 859 (Cal. 2015). That is because *Actavis*’s rejection of  
 7 the scope-of-the-patent test and its concomitant holding that only certain types of patent settlements may  
 8 be subjected to antitrust scrutiny turned on more than just antitrust law and policy.

9 While this Court previously concluded that “*Actavis* turns on questions of antitrust law, not patent  
 10 law,” CA9.ER15, respectfully, that is incorrect. The Supreme Court was unequivocal in *Actavis* that  
 11 “patent and antitrust policies *are both relevant*” to the issue of whether—and if so, under what  
 12 circumstances—a pharmaceutical patent settlement may be subjected to antitrust-style scrutiny. 570 U.S.  
 13 at 148 (emphasis added). Indeed, because federal rights by definition are implicated in cases seeking to  
 14 hold parties liable for settling patent suits, the Supreme Court cautioned that “courts must ‘balance the  
 15 privileges of [the patent holder] and its licensees under the patent grants with the prohibitions of [antitrust  
 16 law] against combinations and attempts to monopolize.’” *Id.* (citation omitted). Accordingly, California  
 17 does not have authority to strike a different balance between competition law and federal patent law; “state  
 18 regulation of intellectual property must yield to the extent that it clashes with the balance struck by  
 19 Congress in our patent laws.” *Bonito Boats*, 489 U.S. at 152. So while California may prefer a different  
 20 set of balances than the one the federal government has struck—and it clearly does, *see Hearing on AB 824*  
 21 *Before the Cal. Assembly Comm. on Health* at 7, 2019-20 Reg. Sess. (Mar. 26, 2019) (“This bill establishes  
 22 a different standard of review for pay-for-delay agreement than what was decided in [*Actavis*].”),  
 23 <https://bit.ly/31IfPiS>—that is not a choice the Constitution permits. AB 824 is preempted.

### 24 C. AB 824 Violates the Prohibition on Excessive Fines.

25 Under AB 824, “[e]ach *person*” who merely “*assists* in [a party’s] violation ... shall forfeit and  
 26 pay ... a civil penalty” of no less than “*twenty million dollars*,” even if he or she “has not received anything  
 27 of value” as a result of his or her role. § 134002(e)(1)(A) (emphases added). Penalties that start at \$20  
 28 million and go up from there are plainly excessive vis-à-vis any individual—such as “junior associate or

1 legal secretary”—who merely assists in settling a lawsuit and derives no value therefrom. CA9.ER16; *see*  
 2 *generally United States v. Mackby*, 261 F.3d 821, 829 (9th Cir. 2001).

3 The AG has previously argued that this is an “as-applied” challenge that cannot be brought until  
 4 after the AG actually tries to impose such a penalty. That misunderstands AAM’s claim. AAM’s claim  
 5 is that there is *no set of circumstances* under which the *minimum* penalty AB 824 authorizes could  
 6 constitutionally be applied *to a person* who has not received anything of value as a result of her role. That  
 7 claim “is ‘facial’ in that it is not limited to [a] particular case, but challenges application of the law more  
 8 broadly,” and it is “‘as applied’ in the sense that it does not seek to strike the [penalty] in all its applications,  
 9 but only to the extent it” applies to *persons* who received no value. *Doe v. Reed*, 561 U.S. 186, 194 (2010).  
 10 The relevant question is thus whether AAM can “satisfy our standards for a facial challenge to the extent  
 11 of th[e] reach” it is seeking to have the law enjoined, *i.e.*, to *persons* who received no value from their  
 12 assistance. *Id.* The answer to that question is clearly “yes.” Indeed, no one could seriously claim that  
 13 there are circumstances under which a \$20-million penalty would *not* be “grossly disproportionate” vis-  
 14 à-vis an individual (like an associate at a law firm representing one of the parties or a secretary who works  
 15 for one of the parties’ CEOs) who did not receive anything of value” as a result of her assistance.

16 Nor does prudence counsel in favor of waiting for the AG to bring an enforcement action and seek  
 17 to impose such an obviously unconstitutional penalty. Once the AG has initiated an enforcement action,  
 18 the abstention doctrine reflected in *Younger v. Harris*, 401 U.S. 37 (1971), and its progeny would prevent  
 19 an individual who allegedly assisted in a violation from seeking a federal injunction precluding AB 824’s  
 20 penalty provisions from being applied to him or her. After all, *Younger* “forbids federal courts to stay or  
 21 enjoin pending state court proceedings” like the ones that would be brought under AB 824. *Id.* at 41; *see*  
 22 *Middlesex Cty. Ethics Comm. v. Garden State Bar Ass’n*, 457 U.S. 423, 439 (1982) (extending *Younger*  
 23 abstention to civil proceedings that may result in the imposition of state-law penalties). Under the *Younger*  
 24 doctrine, therefore, the *only* time in which one could bring a federal action challenging the constitutionality  
 25 of potential state-law penalties is *before* state proceedings are pending—*i.e.*, now. *See Steffel v.*  
 26 *Thompson*, 415 U.S. 452, 475 (1974) (“[A] refusal on the part of the federal courts to intervene when no  
 27 state proceeding is pending may place the hapless plaintiff between the Scylla of intentionally flouting  
 28 state law and the Charybdis of forgoing what he believes to be constitutionally protected activity....”).

**D. AB 824's Burden-Shifting Regime Violates Due Process.**

A statute violates the Due Process Clause when it not only shifts the burden of persuasion to the defendant, but imposes a presumption of liability that carries sanctions but that is effectively impossible for the defendant to rebut. *W. & Atl. R.R. v. Henderson*, 279 U.S. 639, 642 (1929). Such is the case here. The statute stacks the deck against defendants, in violation of due process.

AB 824 “presume[s]” a settlement is “a violation” if the generic (A) “receives anything of value” and (B) “agrees to limit or forego research, development, manufacturing, marketing, or sales of [its] product for any period of time.” § 134002(a)(1). Given the broad definition of “value,” which includes any “exclusive license,” § 134002(a)(1)(A), that presumption covers a broad swath of settlements. To rebut the presumption, a generic must prove either that “[t]he value [it] received” under the agreement “is a fair and reasonable compensation solely for other goods or services that [it] has promised to provide,” or that “[t]he agreement has directly generated procompetitive benefits” that “outweigh [its] anticompetitive effects.” § 134002(a)(3). And in evaluating whether a defendant has made that showing, the factfinder is forbidden from presuming that a patent “is enforceable” or that generic entry “could not have occurred until the expiration of the relevant patent exclusivity.” § 134002(b).

Continuing to stack its anti-defendant presumptions, AB 824 erects another presumption that the relevant product market includes only the branded drug product and its generic substitutes. § 134002(c). That is a stark departure from long-settled law, which defines the relevant market to include all potentially interchangeable products. *See, e.g., Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (federal); Cal. Bus. & Profs. Code § 4073(a) (California). It also makes it even more difficult to rebut the statute’s initial presumption of anti-competitiveness, by assuming that settling parties have the market power to harm competition even when they do not. The reason established precedent does not define the market as limited to the brand drug and its generic equivalent is simple: Drugs often compete against reasonable therapeutic substitutes that are not brand-generic equivalents, and federal courts have recognized that the antitrust product market must include all of those therapeutic substitutes. *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 433-38 (3d Cir. 2016). AB 824 renders these real-world marketplace dynamics effectively irrelevant to the inquiry, thus making defendants’ burden even more onerous.

1 In short, AB 824 makes it effectively impossible to rebut its initial presumption of liability. But  
 2 states may not impose liability “without first providing [defendants] with ‘an opportunity to present every  
 3 available defense,’” *Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007) (citation omitted), and the  
 4 most basic antitrust defense—that the procompetitive effects of the conduct will outweigh any short-term  
 5 barriers to competition—cannot be eliminated by presumption. By allowing the imposition of liability  
 6 (and penalties) based on what amounts to an irrebuttable presumption, AB 824 violates due process.

7 **II. AAM’s Members Will Suffer Irreparable Harm Absent An Injunction, And The Balance Of**  
 8 **Hardships And Public Interest Favor The Injunction.**

9 1. Only an injunction barring enforcement of the statute can prevent AAM’s members from  
 10 suffering further irreparable harm. AB 824 has already caused multiple AAM members to lose favorable  
 11 settlement offers and the value associated with them, and thus has caused these members to spend huge  
 12 sums of money litigating patent cases that they otherwise would have settled. That economic injury  
 13 continues as those unsettled patent cases continue and will recur in future cases. And all of those dollars  
 14 spent and dollars lost constitute irreparable injury by definition, given the AG’s Eleventh Amendment  
 15 immunity. *See Cal. Pharmacists Ass’n v. Maxwell-Jolly*, 563 F.3d 847, 852 (9th Cir. 2009), *vacated on*  
 16 *other grounds*, 565 U.S. 606 (2012). Furthermore, subjecting AAM’s members to a law that violates their  
 17 constitutional rights constitutes irreparable injury on its own. *See, e.g., Elrod v. Burns*, 427 U.S. 347, 373  
 18 (1976) (plurality op.); 11A Charles A. Wright et al., *Federal Practice & Procedure* § 2948.1 (3d ed.).

19 2. Every day AB 824 remains on the books, the flow of generic/biosimilar medicines onto the  
 20 market slows. It has already led to delays in the availability of generic medicines, and it has already driven  
 21 generic manufacturers to withdraw Paragraph IV ANDAs. *See* Ex. F ¶¶ 9-10. The inevitable result of  
 22 leaving AB 824 on the books will be that the savings generic and biosimilar medicines bring will be lost.  
 23 Given that many brand-name drugs are protected by multiple patents, that ANDAs usually trigger  
 24 litigation, that the success rate of such litigation is no better than fifty-fifty, and that such litigation  
 25 typically costs many millions of dollars per side, there is usually no viable alternative to settlement for  
 26 lawfully bringing generic and biosimilar medicines onto the market in a timely manner. The inevitable  
 27 effect of AB 824, therefore, will continue to be more of what we have already seen (as reflected in the  
 28 accompanying declarations)—scuttling patent settlements and the cost savings they bring to patients.

Against those public ills, the harms to the AG will be *de minimis*. Granting the requested injunction will not materially affect California’s efforts to protect its consumers, as the AG (and private parties) will still be able to bring enforcement actions under federal antitrust law, which unlike state law is not bound by the restrictions of the dormant Commerce Clause. Nor will enjoining AB 824’s enforcement harm the AG in any other cognizable way, as a state official “is in no way harmed by issuance of an injunction that prevents the state from enforcing unconstitutional restrictions.” *Legend Night Club v. Miller*, 637 F.3d 291, 302-03 (4th Cir. 2011).

Finally, enjoining AB 824 will help ensure that patients who need access to lower-cost medicines are able to obtain them under the federal system Congress, and that an unconstitutional statute is not enforced. In contrast, leaving AB 824 on the books will produce more of what we have already seen—scuttled patent settlements, withdrawn ANDAs, and delays in generic entry, all of which will drive up prescription drug prices, decrease competition, and harm patients. The balance of equities and public interest decidedly support AAM’s request for injunctive relief.

### CONCLUSION

For the foregoing reasons, the Court should grant AAM’s motion for preliminary injunction.

Respectfully submitted,

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